

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant :	Sharon Mi Lyn Tan	Art Unit :	3763
Serial No. :	10/690,436	Examiner :	LoAn H. Thanh
Filed :	October 22, 2003	Conf. No. :	3696
Title :	CATHETER WITH A SIDEARM FOR DELIVERY OF ANTIMICROBIAL AGENTS TO PREVENT INFECTION		

Mail Stop Appeal Brief - Patents

Commissioner for Patents
P.O. Box 1450
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REPLY BRIEF

Pursuant to 37 C.F.R. §41.41, Appellant responds to the Examiner's Answer as follows.

The Examiner's Answer said:

With respect to Appellant's argument on page 5 of the brief, the Examiner is taking the position that the claims are directed to a device/apparatus and as long as the device of the prior art is capable of performing the function, then it is considered to be anticipated. (Examiner's Answer at 10.)

This statement in support of the pending claim rejections was not made prior to the Examiner's Answer, so Appellant takes this opportunity to address the statement. Appellant finds the statement itself to be unclear. Perhaps the statement is meant to express the view that Liu's needle is capable of performing the function of the catheters covered by claims 1-26. If this is the case, it is Appellant's position that the requisite evidence to support this position is not of record, and that this statement therefore cannot be used as a basis for supporting the pending claim rejections. As stated at §2144.03 of the MPEP :

Ordinarily, there must be some form of evidence in the record to support an assertion of common knowledge. *See Lee*, 277 F.3d at 1344-45, 61 USPQ2d at 1434-35 (Fed. Cir. 2002); *Zurko*, 258 F.3d at 1386, 59 USPQ2d at 1697 (holding that general conclusions concerning what is "basic knowledge" or "common sense" to one of ordinary skill in the art without specific factual findings and some concrete evidence in the record to support these findings will not support an obviousness rejection).

Moreover, Appellant believes that there is relevant evidence in the record that relates to this issue. Specifically, as previously argued by Appellant on numerous occasions, Liu clearly distinguishes a needle from a catheter. (See, e.g. Appeal Brief at 5.) This evidence, which actually is in the record, cannot be negated by an assertion that is made without any citation of evidentiary support in the record.

The Examiner's Answer also said:

With respect to appellant's arguments on page 6, the Examiner is maintaining the position that it would have been obvious to one of ordinary skill in the medical/surgical art to prevent contamination or leaking of fluids since in the medical/surgical field contamination is a problem that medical personnel find necessary in the health care to prevent and maintain sterile environment/instruments as much as possible. With respect to the leaking of the fluids, in preventing contamination medical personnel are fully motivated to further prevent leaking as a further improvement to a device to prevent contamination or patient from bleeding out. (Examiner's Answer at 10-11.)

This argument in support of maintaining the pending claim rejections is now raised for the first time, so Appellant takes this opportunity to reply to the argument. First, there is no evidence provided to support the argument, and the argument therefore cannot be used in maintaining the pending rejections of the claims. (MPEP §2144.03.) Further, while the argument seems to indicate that adding a cap to Liu's device, which already has a mechanism for preventing leaks (see, e.g. Appeal Brief at 5-6), would be desirable because it would further reduce leaks and/or contamination, it is not at all apparent that such a modification would actually be desirable. Appellant is unaware of any evidence of record that indicates that Liu's approach to preventing leaks does not work. Accordingly, there seems to be no support in the record that explains why one skilled in the art would have been motivated to go through the additional cost and complexity associated with adding a cap to Liu's device.

The Examiner's Answer further said:

With respect to the rejection under Liu et al. in view of Davidson and further in view of Fields, Appellant does not have any convincing argument other than there

is “no suggestion to combine these references”. In response to applicant’s argument that there is no suggestion to combine the references,, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, guide wires are well known to have caps or some sort of handling element/mechanism to assist in handling/holding the guidewire at the proximal end/portion. It would have been obvious to one of ordinary skill in the medical/surgical art to modify the guidewire/intervention device of to have a cap in order to manipulate/maneuver the device without physically contacting the guidewire/intervention device at points which would contaminate the patient/caregiver. (Examiner’s Answer at 10.)

This argument in support of maintaining the pending claim rejections is also now raised for the first time, so Appellant takes this opportunity to address the argument. The argument itself seems to raise two issues.

The first issue is raised by the first sentence in the quotation. Appellant is frankly quite surprised that such a comment would be made as it is absolutely incorrect. If nothing else, the Appeal Brief states that “contrary to the Examiner’s characterization, Liu does not disclose the catheter/side-arm tube combination required by claims 1-26”. (Appeal Brief at 7.) Further, throughout pages 5 and 6 of the Appeal Brief, Appellant argues against the combination of Liu and Davidson. (*Id.* at 5-6.) While page 5 and 6 of the Appeal Brief address a rejection based on Liu, Davidson and *Fischell*, given the manner in which the rejections were written, the statements regarding combining Liu and Davidson are equally applicable to a rejection based on Liu, Davidson and *Fields*. Moreover, with regard to the rejection based on the combination of Liu, Davidson and *Fields*, the Appeal Brief states “even if the references were combined, the result would not be the subject matter covered by claims 1-26.” (*Id.* at 7.)

The second issue relates the last two sentences in the above-quoted language. No evidence is provided to support this argument, so the argument cannot be relied upon in maintaining the pending claim rejections. (MPEP §2144.03.)

Appellant does not request an oral hearing.

Applicant : Sharon Mi Lyn Tan
Serial No. : 10/690,436
Filed : October 22, 2003
Page : 4

Attorney's Docket No. 01194-513001

For these reasons, and the reasons stated in the Appeal Brief, Appellant submits that the final rejection should be reversed.

Please apply any charges or credits to Deposit Account No. 06-1050, referencing Attorney Docket No. 01194-513001.

Respectfully submitted,

Date: December 5, 2007

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